

AMENDMENT OF THE CLAIMS

Please amend the claims as follows. This listing of claims will replace all prior versions and listings of claims in the application.

1. (Canceled)
2. (Withdrawn) A method for inducing cell death in prostate cancer cells, the method comprising treating androgen responsive and androgen independent prostate cancer cells with an effective amount of a Tumor necrosis factor α - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and an effective amount of an antiprogestin, such that the combination of the TRAIL and the antiprogestin increases the level of at least one of the DR4 or the DR5 death receptors in at least a portion of the treated prostate cancer cells and induces apoptosis in a greater number of the treated cancer cells than the additive effect of TRAIL and the antiprogestin separately applied to the cancer cells.
3. (Withdrawn) The method of claim 2, wherein the antiprogestin comprises Mifepristone.
4. (Withdrawn) A method for treating prostate cancer by inducing cell death in cancer cells, the method comprising treating androgen responsive and androgen independent prostate cancer cells with a pharmaceutical composition comprising an effective amount of a Tumor necrosis factor α - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and an effective amount of Mifepristone, such that the combination of the TRAIL and the Mifepristone increases the level of at least one of the DR4 or the DR5 death receptors in at least a portion of the treated prostate cancer cells and induces apoptosis in a greater number of the treated cancer cells than the additive effect of TRAIL and the Mifepristone separately applied to the cancer cells.

5. (Withdrawn) The method of claim 4, wherein the cancer cells are treated with Mifepristone prior to being treated with TRAIL polypeptide.
6. (Withdrawn) The method of claim 4, wherein the cancer cells are treated with Mifepristone and TRAIL polypeptide concurrently.
7. (Withdrawn) The method of claim 4, wherein the dose of TRAIL polypeptide in the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 1 to 1,000 ng/ml.
8. (Withdrawn) The method of claim 4, wherein the dose of TRAIL polypeptide in the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 200 to 600 ng/ml.
9. (Withdrawn) The method of claim 4, wherein the dose of TRAIL polypeptide in the pharmaceutical composition results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 350 to 450 ng/ml.
10. (Withdrawn) The method of claim 4, wherein the dose of Mifepristone in the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer which ranges from 1 to 1,000 μ M.
11. (Withdrawn) The method of claim 4, wherein the dose of Mifepristone in the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer which ranges from 1 to 100 μ M.
12. (Withdrawn) The method of claim 4, wherein the dose of Mifepristone in the pharmaceutical composition results in a local concentration of Mifepristone at the prostate cancer which ranges from 5 to 20 μ M.

Claims 13-17 (Canceled)

18. (Withdrawn) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with an increase in an activated caspase enzyme in at least a portion of the treated ~~androgen responsive and androgen independent~~ prostate cancer cells.

19. (Withdrawn) The method of claim 18, wherein the activated caspase enzyme comprises at least one of caspase-8, caspase-7, caspase-9, or caspase-3.

20. (Withdrawn) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with an increase in truncated BID protein (tBid) in at least a portion of the treated ~~androgen responsive and androgen independent~~ prostate cancer cells.

21. (Withdrawn) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone is associated with a reduction of mitochondrial cytochrome c in at least a portion of the treated ~~androgen responsive and androgen independent~~ prostate cancer cells.

22. (Withdrawn) The method of claim 4, wherein the treatment of cancer cells with TRAIL polypeptide and Mifepristone results in an increase in apoptosis formation in at least a portion of the treated ~~androgen responsive and androgen independent~~ prostate cancer cells.

23. (Canceled)

24. (Canceled)

25. (Withdrawn) The method of claim 4, wherein the manner of treatment comprises intravenous injection of said pharmaceutical composition.

26. (Withdrawn) The method of claim 4, in combination with other means of treatment such as surgery, chemotherapy, or radiation therapy.

27. (Canceled)

28. (Currently amended) A composition for treating prostate cancer by inducing cell death in androgen responsive and androgen independent prostate cancer cells comprising an effective amount of a Tumor necrosis factor α - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and an antiprogestin in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL polypeptide and antiprogestin to induce apoptosis in at least a portion of the androgen responsive and androgen independent prostate cancer cells exposed to the composition and to increase the level of at least one of the DR4 or the DR5 death receptors in at least a portion of the prostate cancer cells exposed to the composition, such that the combination of the TRAIL and the antiprogestin induces apoptosis in a greater number of the treated prostate cancer cells than the additive effect of TRAIL and the antiprogestin separately applied to the cancer cells.

29. (Original) The composition of claim 28, wherein the antiprogestin comprises Mifepristone.

30. (Currently amended) A composition for treating prostate cancer by inducing cell death in androgen responsive and androgen independent prostate cancer cells comprising an effective amount of a Tumor necrosis factor α - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 and Mifepristone in a pharmaceutical carrier, wherein an effective amount comprises sufficient TRAIL polypeptide and Mifepristone to induce apoptosis in at least a portion of the androgen responsive and androgen independent prostate cancer cells exposed to the composition and to increase the level of at least one of the DR4 or the DR5 death receptors in at least a portion of the prostate cancer cells exposed to the composition,

such that the combination of the TRAIL and the Mifepristone induces apoptosis in a greater number of the treated prostate cancer cells than the additive effect of TRAIL and the Mifepristone separately applied to the cancer cells.

31. (Previously presented) The composition of claim 30, wherein the Mifepristone and the TRAIL polypeptide are packaged in such a manner that the Mifepristone is at least partially released for application to the cancer prior to the release of the TRAIL polypeptide.

32. (Previously presented) The composition of claim 30, wherein the Mifepristone and the TRAIL polypeptide are packaged in such a manner so as to be released substantially simultaneously.

33. (Previously presented) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 1 to 1,000 ng/ml.

34. (Previously presented) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 200 to 600 ng/ml.

35. (Previously presented) The composition of claim 30, wherein the dose of TRAIL polypeptide results in a local concentration of TRAIL polypeptide at the prostate cancer which ranges from 350 to 450 ng/ml.

36. (Previously presented) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer which ranges from 1 to 1,000 μ M.

37. (Previously presented) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer which ranges from 1 to 100 µM.

38. (Previously presented) The composition of claim 30, wherein the dose of Mifepristone results in a local concentration of Mifepristone at the prostate cancer which ranges from 5 to 20 µM.

Claims 39-41 (Canceled)

42. (Currently amended) A kit for pharmaceutical treatment of androgen responsive and androgen independent prostate cancer comprising:

- (a) a pharmacologically effective amount of a Tumor necrosis factor α - Related Apoptosis Inducing Ligand (TRAIL) polypeptide comprising the amino acid sequence SEQ ID NO: 1 packaged in a sterile container;
- (b) a pharmacologically effective amount of an antiprogestin packaged in a sterile container, wherein an effective amount comprises an amount of TRAIL polypeptide and antiprogestin sufficient to induce apoptosis in a greater number of androgen responsive and androgen independent prostate cancer cells than the additive effect of the TRAIL and the antiprogestin separately applied to the cancer cells and to increase the levels of at least one of the DR4 or the DR5 death receptors in at least a portion of the prostate cancer cells;
- (c) at least one aliquot of a pharmaceutical carrier; and
- (d) instructions for application of the TRAIL polypeptide and the antiprogestin to a patient having prostate cancer such that application of both the TRAIL and the antiprogestin induces apoptosis at least a portion of the treated prostate cancer cells.

43. (Previously presented) The kit of claim 42, wherein the antiprogestin comprises Mifepristone.

Claims 44-46 (Canceled)

47. (Previously presented) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in an increase in an activated caspase enzyme in at least a portion of the treated prostate cancer cells.

48. (Previously presented) The composition of claim 47, wherein the activated caspase enzyme comprises at least one of caspase-8, caspase-7, caspase-9, or caspase-3.

49. (Previously presented) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in an increase in truncated BID protein (tBid) in at least a portion of the treated prostate cancer cells.

50. (Previously presented) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in a reduction of mitochondrial cytochrome c in at least a portion of the treated prostate cancer cells.

51. (Previously presented) The composition of claim 28, wherein an effective amount of the TRAIL polypeptide and antiprogestin results in an increase in apoptosome formation in at least a portion of the treated prostate cancer cells.

52. (Previously presented) The composition of claim 28, wherein the antiprogestin and the TRAIL polypeptide are packaged in such a manner that the antiprogestin is at least partially released for application to the cancer prior to the release of the TRAIL polypeptide.